UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,308	09/01/2006	Marcel Minor	207,808	9258

7590 11/12/2009

Abelman Frayne and Schwab
666 Third Avenue
New York, NY 10017-5621

EXAMINER	
KRAUSE, ANDREW E	
ART UNIT	PAPER NUMBER
1794	
MAIL DATE	DELIVERY MODE
11/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,308	MINOR ET AL.	
	Examiner	Art Unit	
	ANDREW KRAUSE	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) *22-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Listing of Claims

1. Claims 22-41 are pending. Claims 22-36 are withdrawn. Claims 37 and 39 are amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. **Claims 39-41** are rejected under 35 U.S.C. 103(a) as unpatentable over Sharma (US 4,797,288) in view of Fuglsang (US 2002/0094367).

5. **Regarding claim 37**, Sharma discloses a method of preparing a granules suitable for foodstuffs having an average diameter of 200-30 mesh (75-500 microns) (column 8, lines 22-24) and comprising, for example;

a. 38% of non-lipophilic particles with an average diameter of 100 mesh (149 microns) including 20% functional food ingredient (aspartame); and

b. 62% of a discrete continuous phase comprising lipids, which envelopes the non-lipophilic particles and holds them together, and is formed into an agglomerate with a diameter in the range of 200 mesh (75 microns)-50 mesh (300 microns) ((column 6, line 55-column 7, line 18, Example 7, also see above).

6. Sharma further discloses enveloping this agglomerate with an exterior lipophilic layer having a melting point of 35-38 C (see column 7, lines 19-36, and above) in an amount of, While exterior coatings in amounts of 200% are found to effectively mask taste, Sharma suggests that the exterior coating may be used in amounts as low as 30% of the weight of the core material (col. 8, lines 10-21). Given this disclosure, one having ordinary skill in the art at the time of the invention would find it obvious to adjust the thickness of the exterior coating layer in order to adjust the release rate of the functional ingredient, as doing so would require only the optimization of a result effective variable.

7. Sharma discloses incorporating this composition into baked goods (column 8, lines 31-32), but fails to explicitly disclose the use of the granules as a bread improver. However, Fuglsang, like Sharma discloses functional ingredients for incorporation into foodstuffs which are coated with a lipid substance in order to control the release of the functional ingredient into the surrounding foodstuff ([0017]-[0029]). The functional ingredients disclosed in Fuglsang are enzymes, which can be used as dough conditioners or improvers ([0004]-[0005]). Given the teachings of Sharma and Fuglsang, one having ordinary skill in the art at the time of the invention would have found it obvious to modify the lipid coated, controlled release functional food ingredient of Sharma by incorporating enzymes as the functional ingredient as in Fuglsang, as the coating of Sharma is effective for allowing the artisan to control the time of release of the functional ingredient, which is a goal shared by Fuglsang.

8. Regarding claim 38, Fuglsang further discloses adding lipid encapsulated enzyme dough conditioners to bread doughs but does not disclose the quantity added in terms of weight, but rather in terms of enzyme activity. One having ordinary skill in the art at the time of the invention would find it obvious to adjust the weight of encapsulated enzyme added to the dough in order to control the influence of the dough conditioner texture and volume of the bread for the intended purpose (Example 3).

9. **Regarding claim 39**, Sharma discloses a method of preparing a granules suitable for foodstuffs having an average diameter of 200-30 mesh (75-500 microns) (column 8, lines 22-24) and comprising, for example;

c. 38% of non-lipophilic particles with an average diameter of 100 mesh (149 microns) including 20% functional food ingredient (aspartame); and

d. 62% of a discrete continuous phase comprising lipids, which envelopes the non-lipophilic particles and holds them together, and is formed into an agglomerate with a diameter in the range of 200 mesh (75 microns)-50 mesh (300 microns) ((column 6, line 55-column 7, line 18, Example 7, also see above).

10. Sharma further discloses enveloping this agglomerate with an exterior lipophilic layer having a melting point of 35-38 C (see column 7, lines 19-36, and above). Sharma discloses that the thickness of the coating can be modified in order to achieve the proper rate of release of the functional ingredient. While exterior coatings in amounts of 200% are found to effectively mask taste, Sharma suggests that the exterior coating may be used in amounts as low as 30% of the weight of the core material (col. 8, lines 10-21). Given this disclosure, one having ordinary skill in the art at the time of the invention would find it obvious to adjust the thickness of the exterior coating layer in order to adjust the release rate of the functional ingredient, as doing so would require only the optimization of a result effective variable.

11. Sharma discloses a method of coating functional food ingredients (core material) such as drugs or sweeteners with a molten lipid material. Example 7 discloses providing non-lipophilic particular ingredients including about 80 % of 100 mesh (149 micron) KCl salt in and about 20% aspartame as a flavorant (column 13, lines 1-4). Sharma discloses mixing this core material with a molten fatty acid or wax to create a uniform dispersion of the core material and then spray congealing (spray chilling) the uniform dispersion into agglomerates in which a plurality of the core materials are enveloped by a discrete continuous lipid phase, and where the agglomerates are sieved to have an average diameter in the range of about 200 mesh (75 microns)-50 mesh (300 microns) ((column 6, line 55-column 7, line 18, Example 7).

12. Sharma further discloses coating the agglomerates with a second coating comprising molten lipid material using fluidized bed coating to produce uniformly coated agglomerates (column 7, lines 19-36, 54-59).

13. Regarding the melting points of the molten lipid materials, Sharma discloses that the delivery system preferably has a melting range of about 35 C to about 38 C, thereby providing melting temperatures in the range of 30-45 C, and also keeping the melting temperature of the second molten lipid material within 5 degrees Celsius of the continuous lipid phase (column 7, lines 19-36).

14. Although Sharma does not explicitly disclose the steps of cooling the coated agglomerates to ambient temperature and collecting the coated agglomerates to obtain the granulate, it is obvious to one having ordinary skill in the art that following the use of the fluidized bed, the granulates will intrinsically cool to room temperature. It is further obvious that the coated agglomerates are being collected to obtain the granulate, as said granulate is later incorporated into baked goods, food products and the like (column 8, lines 30-48).

15. Sharma differs in that the functional core material does not include enzymes or oxioreductants. However, Fuglsang, like Sharma discloses functional ingredients for incorporation into foodstuffs which are coated with a lipid substance in order to control the release of the functional ingredient into the surrounding foodstuff ([0017]-[0029]). The functional ingredients disclosed in Fuglsang are enzymes. Given the teachings of Sharma and Fuglsang, one having ordinary skill in the art at the time of the invention would have found it obvious to modify the lipid coated, controlled release functional food ingredient of Sharma by incorporating enzymes as the functional ingredient as in Fuglsang, as the coating of Sharma is effective for allowing the artisan to control the time of release of the functional ingredient, which is a goal shared by Fuglsang.

Response to Arguments

16. Applicant's arguments, see remarks, filed 7/1/09, with respect to the rejection under 35 U.S.C. 112 have been fully considered and are persuasive. The ground of rejection has been withdrawn.

17. Regarding applicant's arguments with respect to the amended claims, the arguments are believed to be addressed by the rejection set forth above. Further, regarding applicants assertion that "Sharma teaches away from granules in which the exterior coating represents not more than 50 wt. % of the total granules", Sharma discloses that the size of the exterior layer can be varied in order to control the rate of release of the functional ingredient agglomerate encapsulated therein. While amounts ranging from 200-400% (which would result in an exterior coating representing 66.7% of the total granules) are preferred in Sharma, it is further disclosed that the exterior layer may be as small as 30% of the weight of the core. Given this disclosure, Sharma does not teach away from having relatively less massive exterior coatings, but rather that the size of the exterior layer allows the artisan to adjust the release properties of the functional ingredient.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW KRAUSE whose telephone number is (571)270-7094. The examiner can normally be reached on 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571)272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ANDREW KRAUSE/
Examiner, Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794